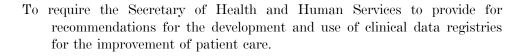
[DISCUSSION DRAFT]

H.R.

113TH CONGRESS 2D Session



IN THE HOUSE OF REPRESENTATIVES

Mr. OLSON introduced the following bill; which was referred to the Committee on _____

A BILL

- To require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,

3 SECTION 1. RECOMMENDATIONS FOR DEVELOPMENT AND

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USE OF CLINICAL DATA REGISTRIES.

5 (a) IN GENERAL.—Not later than one year after the
6 date of the enactment of this Act, the Secretary of Health
7 and Human Services shall make recommendations for the

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development and use of clinical data registries that are
 integrated with clinical practice guidelines and best prac tices or standards of care for the improvement of patient
 care. The Secretary shall make such recommendations
 available to the public by posting them on a public Website
 of the Department of Health and Human Services.

7 (b) SPECIFIC RECOMMENDATIONS.—Such rec8 ommendations, with respect to such registries, shall in9 clude the following:

10 (1) Recommendations for a set of standards
11 that, if adopted, would allow for the bidirectional,
12 interoperable exchange of information between the
13 electronic health records of the reporting clinicians
14 and such registries.

15 (2) Recommendations on how clinical registries, 16 including outcomes-based registries, may be devel-17 oped and then used to evaluate various care models 18 and methods, including improved clinical care co-19 ordination, and the impact of such models and meth-20 ods on the management of diseases as measured by 21 appropriate care parameters based on clinical prac-22 tice guidelines and best practices (such as A1C, 23 blood pressure, and cholesterol levels in the case of diabetes). 24

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1 (3) Recommendations on how such registries 2 should be structured to facilitate the recording and 3 reporting of post-market data for the purposes of 4 monitoring safety and efficacy of FDA-approved de-5 vices and drugs, reporting relevant clinical data to 6 satisfy attestation requirements for coverage of pre-7 scribed devices and drugs, and better defining appro-8 priate clinical use in support of evidence develop-9 ment for the Medicare program (such as improving 10 patient access to safe and effective glucose moni-11 toring systems and future glucose monitoring tech-12 nologies).

13 (4) Recommendations on how data from such 14 registries may be used to inform physicians and 15 other health care professionals regarding clinical 16 practices for the prevention of diseases (such as dia-17 betes and the precursor conditions of diabetes) and 18 appropriate methods for the dissemination of clinical 19 practice support tools and other educational re-20 sources that may be derived from registry data.

(5) Recommendations for how registries can be
used to track utilization of preventive health benefits
and their impact, such as screenings and the Medicare annual wellness visits that may reduce the risk
of chronic diseases, such as obesity, osteoporosis,

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cardiovascular disease, cancer, diabetes and their
 complications.

3 (c) CONSULTATION WITH CLINICAL EXPERTS.—The 4 Secretary shall consult with national medical specialty so-5 cieties in the development of such recommendations as 6 they relate to the diseases that they manage and treat 7 (such as with the American Association of Clinical 8 Endocrinologists with respect to recommendations relating 9 to diabetes and pre-diabetes conditions).